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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,066	08/23/2001	Hisakazu Katsuki	KATSUKI=1	8579

1444 7590 12/28/2004

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,066	KATSUKI, HISAKAZU	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-14,16,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-14,16,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A41615

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, Amendment, and Declaration filed 09/15/04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-14, 16 and 19-20 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Lacy et al (US 6,096,338) in view of Amey et al (LJS 6,080,426).

Lacy et al (US 6,096,338) teaches a delivery system for hydrophobic drugs in which the carrier comprises a digestible oil and a surfactant (column 4, lines 1-7). The preferred digestible oils include vegetable oils such as soybean oil (column 9, lines 35-

56). Among the hydrophobic drugs which may be formulated in accordance with the disclosed invention, probucol, is indicated (column 13, line 4). The concentration of drug in the final formulation will be that which is required to provide the desired therapeutic effect from the drug concerned, but will generally lie in the range of 0.1% to 50% by weight (column 13, lines 25-29). The compositions for oral administration may be solid, liquid or semi-solid such as liquid oral dosage forms filled into hard or soft gelatin capsules (column 14, lines 52-58).

The capsule of Lacy does not expressly teach that the soft gelatin capsules contain sorbitol. However, Amey supplies this
Deficiency by teaching that it is well known within the pharmaceutical dosage units arts to include components such as sorbitol within a gelatin based capsule shell (column 3, lines 30).

While the reference does not expressly teach applicant's claimed percent weight of sorbitol or gelatin, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 IJSPQ 233, 235 (CGA 1955).

Regarding the limitation that the shell thickness is from 28x10-3 inches to 4Ox10'3 inches, the examiner determines that this limitation fails to impart a patentable distinction upon the claimed invention. It is the position of the examiner that these are limitations that would be routinely determined by one of ordinary skill in the art, through

minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

The Amey reference does not expressly state that the capsules are soft. However, there is a suggestion that the capsules shells may indeed present as soft dosage forms due to the presence of the relative amounts of plasticizer as well as lubricant and extender (column 3, lines 29-55). Accordingly it would be obvious to one of ordinary skill in the pharmaceutical arts to combine the teachings of Lacy with the teachings of Amey. The expectation would be that by manipulating factors such as adding sorbitol to the carrier capsule, enhanced solubility, thus enhanced bioavailability is obtained of the active ingredient.

Response to Arguments

Applicant's arguments filed 09/15/04 have been fully considered but they are not persuasive.

Applicant arguments and Declaration disclosed that Lacy does not teach the claimed drug which is 4,6-di-tert-butyl-2,2-di-n-pentyl-5-hydroxy-2,3-dihydrobenzofuran. Accordingly, the 102(e) rejection has been withdrawn. However, the 103(a) rejection is maintained because Lacy teaches the derivative of the claimed drug, namely probucol. Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine and select suitable compound, for example the claimed drug

compound to obtain the claimed invention, because Lacy also recognizes the desirability of obtaining a stable capsule formulation.

Applicant argues that Amey has not been cited to make up for the aforementioned deficiencies of Lacy as pointed out in the 102(e) argument. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

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